DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2014

Sun Nuclear Corporation
% Ms. Noel Downey
Project Manager
3275 Suntree Boulevard
MELBOURNE FL 32940

Re: K142431
Trade/Device Name: Model 1203 - WaterProof Profiler
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 5, 2014
Received: November 10, 2014

Dear Ms. Downey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142431

Device Name
Model 1203 – Waterproof Profiler

Indications for Use *(Describe)*
The Model 1203 WaterProof PROFILER is intended for radiotherapy dosimetry measurements for commissioning a treatment planning system (TPS) computer. It is also intended for periodic beam quality assurance (QA) tests as defined by the medical physicist responsible for the QA program.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 – 510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

August 27, 2014

Submitted by:

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Contact Person:

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Classification Name:

Accelerator, Linear, Medical

Common Name:

Detector Array

Proprietary Names:

Model 1203 WaterProof PROFILER

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Medical charged-particle radiation therapy system
Product code: IYE

Primary Predicate Device:

Model Name:	Model 1174 PROFILER 2
Common Name:	Radiation Field Analyzer
510(k) #	K063021
Manufacturer:	Sun Nuclear Corporation
Submitted:	10/2/2006

Secondary Predicate Device:

Model Name:	Model 1230 3D SCANNER
Common Name:	Water Phantom Ionizing Radiation Dosimetry Scanner
510(k) #	K101992
Manufacturer:	Sun Nuclear Corporation
Submitted:	July 13, 2010

2 Description and Use:

The WaterProof PROFILER, model 1203, is a linear array of radiation detectors that are housed in a water proof enclosure that mounts to the 3D SCANNER's movement mechanisms. The electronics in the array measures charge produced in the detectors due to ionizing radiation. The WaterProof PROFILER provides measurement updates to the 3D SCANNER. The 3D SCANNER correlates the dose information with motor position information and transfers the data to a computer running SNC Dosimetry. SNC Dosimetry then provides a graphical user interface for viewing the measured dose distributions and its parameter analysis; it also provides a tool for exporting the data to treatment planning systems.

The WaterProof PROFILER includes five components:

1. a linear array of radiation detectors;
2. a water proof enclosure;
3. a means for connecting to the 3D SCANNER's movement mechanisms;
4. control electronics and embedded code to manage and transmit the data recorded from the radiation detectors;
5. a cable that connects the water proof enclosure to the 3D SCANNER

The WaterProof PROFILER has applications in:

1. delivery device data collection for commissioning a treatment planning system,
2. quality assurance measurements of a treatment delivery device, and
3. testing of a treatment delivery device at the manufactures facility.

To satisfy the applications above, the WaterProof PROFILER is capable of performing relative dose measurements, which may then be used to calculate QA parameters such as: field edge, field size, beam center, penumbra, wedge angles (dynamic and physical), symmetry and flatness.

3 Intended Use Statements:

The Model 1203 WaterProof PROFILER is intended for radiotherapy dosimetry measurements for commissioning a treatment planning system (TPS) computer. It is also intended for periodic beam quality assurance (QA) tests as defined by the medical physicist responsible for the QA program.

4 Technological Characteristics

The primary technological characteristic of the WaterProof PROFILER is the array geometry, which facilitates measurement of static or dynamic dose deliveries in most beam configurations. The array length is 504mm and detector spacing is 4 mm.

The 1D array of diodes is embedded in a waterproof polycarbonate phantom at a depth of 0.8 g/cm2. Connection to the 3D SCANNER (K101992) provides remote control of positioning in a water bath as well as data acquisition in 100 ms update periods.

5 Performance Data and Comparison with Predicate

The WaterProof PROFILER has been bench tested and shown that these devices perform within their design specifications. Tests that compare known static and dynamic fields required during treatment planning system commissioning have been performed; the results were found to have correlation between the WaterProof PROFILER and its predicate devices.

Performance testing also indicated compliance with relevant electrical safety and EMC standards.

Table of specification differences between WaterProof PROFILER,PROFILER 2 and the 3D SCANNER

	WaterProof PROFILER	PROFILER 2	3D SCANNER
Number of Arrays	1	2	0
Array Length	50.4cm	X: 22.4cm Y: 32.8cm	50cm
Detectors per Array	127	X: 57 Y: 83	1
Detector Density	4mm/detector	4mm/detector	1 detector translated across 50cm
Detector Area	0.8x0.8mm	0.8x0.8mm	User definable
Detector Sensitivity	32nC/Gy	32nC/Gy	User definable
Buildup	1.0 g/cm2	0.8 g/cm2	User definable
Waterproof	Yes	No	User definable
Sampling rate	100ms	100ms	50ms

6 Summary

The Model 1203 WaterProof PROFILER is deemed substantially equivalent to the predicate devices. The intended use, performance testing, safety and effectiveness reviews demonstrate that these devices are as safe, as effective, and perform as well or better than the predicate device. The minor technological differences between the WaterProof PROFILER and the predicates do not raise new types of safety or effectiveness questions.